NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 1503.) The Governor's Office authorized the notice to proceed through the rulemaking process on June 24, 2011.

[R11-99]

PREAMBLE

1. Sections Affected — **Rulemaking Action**
R4-23-411 — Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. § 32-1974

3. A list of all previous notices appearing in the *Register* addressing the proposed rules:

Notice of Rulemaking Docket Opening: 17 A.A.R. 1499, August 5, 2011 *(in this issue)*

4. The name and address of agency personnel with whom persons may communicate regarding the rules:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

5. An explanation of the rules, including the agency's reasons for initiating the rules:

S.B. 1298 passed by the 50th Legislature changed A.R.S. § 32-1974 to allow pharmacists to administer influenza vaccine to a patient who is at least 6 years of age, but under 18 years of age without a prescription based on approved protocols. S.B. 1298 also allows pharmacists to administer immunizations and vaccines to a person who is at least 6 years of age, but under 18 years of age with a prescription order from a medical practitioner based on approved protocols. S.B. 1298 also allows a pharmacy or graduate intern who is certified by the Board to administer immunizations and vaccines under Board rules to do so only in the presence and under the immediate personal supervision of a pharmacist certified by the Board to administer immunizations and vaccines. The rulemaking will amend the language of R4-23-411 (Pharmacist-administered Adult Immunizations) to comply with the requirements of S.B. 1298. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for pharmacist-administered and pharmacy or graduate intern-administered immunizations.

6. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on or not to rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The proposed rules will impact the Board, pharmacists, pharmacies, and the public. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the proposed rule will have moderate economic impact on pharmacists and pharmacies. The rulemaking will allow properly certified pharmacists to administer influenza vaccine to children age 6 to 17 without a prescription order from a medical practitioner and administer any immunization or vaccine to children age 6 to 17 with a prescription order from a medical practitioner. The rulemaking will also allow a Board-certified pharmacy or graduate intern to administer immunizations and vaccines in the presence of and under the immediate personal supervision of a Board-certified pharmacist. This will increase the number of patients a pharmacist may serve and increase the public's access to needed vaccines. Being able to administer vaccines without a prescription will provide pharmacists or pharmacies with opportunity for increased income. The Board estimates that the ability to administer vaccines without a prescription will provide a potential increased income for pharmacies of from 20 to 50 percent.

The proposed rules will have minimal to moderate economic impact on the public. The public will benefit from increased access to immunization services from pharmacists, including reduced time to receive vaccination without the need to obtain a prescription from a medical practitioner. The Board estimates that the public could save from 40 to 60 percent using a pharmacy setting for vaccinations instead of a scheduled doctor's office visit.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for pharmacist-administered or pharmacy or graduate intern-administered immunizations.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, September 6, 2011. An oral proceeding is scheduled for:

Date:	September 6, 2011
Time:	10:00 a.m.
Location:	1700 W. Washington St., 3rd Floor Board Room Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-411. Pharmacist-administered ~~Adult~~ or Pharmacy or Graduate Intern-administered Immunizations

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. Pharmacist-administered ~~Adult~~ or Pharmacy or Graduate Intern-administered Immunizations

A. ~~Authority~~ Certification to administer immunizations, vaccines, and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient. As used in this Section, "eligible adult patient" means an eligible patient 18 years of age or older and "eligible minor patient" means an eligible patient at least 6 years of age but under 18 years of age. A pharmacist or a pharmacy or graduate intern, in the presence of and under the immediate personal supervision of a certified pharmacist, may administer, without a prescription, immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient, if:

1. The pharmacist or pharmacy or graduate intern meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section;
2. The Board certifies the pharmacist or pharmacy or graduate intern as specified in subsection ~~(C)~~ (D);
3. ~~The~~ For an eligible adult patient, the immunization or vaccine is listed in the United States Centers for Disease Control and Prevention's Recommended Adult Immunization Schedule; or the immunization or vaccine is recommended in the United States Centers for Disease Control and Prevention's Health Information for International Travel; ~~and~~
4. ~~The~~ For an eligible adult patient, the immunization or vaccine is not on the Arizona Department of Health Services list specified in A.A.C. R9-6-1301 as required under A.R.S. § 32-1974 and subsection ~~(H)~~ (I);
5. For an eligible minor patient, the immunization or vaccine is for influenza; and
6. For an eligible minor patient, any immunizations or vaccines other than influenza are administered in response to a public health emergency declared by the Governor under A.R.S. § 36-787.

B. A pharmacist or a pharmacy or graduate intern, in the presence of and under the immediate personal supervision of a certified pharmacist, may administer, with a prescription, any immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient, if:

1. The pharmacist or pharmacy or graduate intern meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section;
2. The Board certifies the pharmacist or pharmacy or graduate intern as specified in subsection (D).

~~B.~~C. A pharmacist or pharmacy or graduate intern who ~~has authority~~ is certified to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall ~~not~~:

1. Not delegate the authority to any other pharmacist, pharmacy or graduate intern, or employee; and
2. Maintain their current certificate for inspection by the Board or its designee or review by the public.

~~C.~~D. Qualifications for ~~authorization~~ certification to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient. After receipt of a completed application form, the Board shall issue a certificate authorizing the administration of immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient to a pharmacist or pharmacy or graduate intern who meets the following qualifications:

1. Has a current~~, unrestricted~~ license to practice pharmacy in this state~~;~~,
2. Successfully completes a training program specified in subsection ~~(D)~~ (E),~~;~~ and
3. Has a current certificate in basic cardiopulmonary resuscitation.

~~D.~~E. ~~Pharmacist-administered adult immunizations~~ Immunizations training program requirements. A training program for pharmacists or pharmacy or graduate interns to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall include the following courses of study:

1. Basic immunology and the human immune response;
2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
3. Response to an emergency situation as a result of the administration of an immunization, including administering epinephrine and diphenhydramine to counteract the adverse effects of an immunization given based on a patient-specific prescription order received before administering the immunization;
4. Administration of intramuscular injections;
5. Other immunization administration methods; and
6. Recordkeeping and reporting requirements specified in subsection ~~(E)~~ (F).

~~E.~~F. Recordkeeping and reporting requirements.

1. A pharmacist or pharmacy or graduate intern granted ~~authorization~~ certification under this Section to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible patient shall provide to the pharmacy the following documentation regarding each immunization or vaccine administered:
   a. The name, address, and date of birth of the patient;
   b. The date of administration and site of injection;

c. The name, dose, manufacturer's lot number, and expiration date of the vaccine, epinephrine, or diphenhydramine;
d. The name and address of the patient's primary health care provider or physician, as identified by the patient;
e. The name of the pharmacist or pharmacy or graduate intern administering the immunization;
f. A record of the pharmacist's or pharmacy or graduate intern's consultation with the patient determining that the patient is an eligible patient as defined in R4-23-110;
g. The date and time that the written report specified in subsection ~~(E)(2)~~ (F)(2) was sent to the patient's primary health care provider or physician;
h. Consultation or other professional information provided to the patient by the pharmacist or pharmacy or graduate intern; ~~and~~
i. The name and date of the vaccine information sheet provided to the patient; and
j. For immunizations or vaccines given to an eligible minor patient, a consent form signed by the minor's parent or guardian.

2. The pharmacist or pharmacy or graduate intern shall provide a written report to the patient's primary health care provider or physician containing the documentation required in subsection ~~(E)(1)~~ (F)(1) within 48 hours after the immunization. The pharmacy shall make the required records specified in subsection ~~(E)(1)~~ (F)(1) and a record of compliance with this subsection available in the pharmacy for inspection by the Board or its designee.
3. A pharmacy's pharmacist-in-charge shall maintain the records required in subsection ~~(E)(1)~~ (F)(1) in the pharmacy for a minimum of seven years from the immunization's administration date.

~~F.~~**G.** Confidentiality of records. A pharmacist, pharmacy or graduate intern, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.

~~G.~~**H.** Renewal of a certificate for pharmacist-administered or pharmacy or graduate intern-administered ~~adult~~ immunizations. A certificate authorizing a pharmacist or pharmacy or graduate intern to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient shall be renewed biennially by submitting a renewal request within the 30 days before the certificate's expiration date. A pharmacist or pharmacy or graduate intern desiring to renew the certificate shall provide to the Board proof of the following:
1. Current certification in basic cardiopulmonary resuscitation, and
2. Completion of a minimum of two contact hours (0.2 CEU) of continuing education related to immunizations. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

~~H.~~**I.** Pharmacist-administered or pharmacy or graduate intern-administered adult immunizations that require a prescription order. A pharmacist or pharmacy or graduate intern certified by the Board to administer adult immunizations or vaccines shall not administer any immunization or vaccine listed in A.A.C. R9-6-1301 without a prescription order. In addition to filing a prescription order as required in A.R.S. § 32-1964, a pharmacist or pharmacy or graduate intern who administers an immunization or vaccine listed in A.A.C. R9-6-1301 shall comply with the recordkeeping requirements of subsection ~~(E)(1)~~ (F)(1).

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 1503.) The Governor's Office authorized the notice to proceed through the rulemaking process on June 24, 2011.

[R11-100]

PREAMBLE

1. Sections Affected	Rulemaking Action
R4-23-421	Repeal
R4-23-422	Repeal
R4-23-423	Repeal
R4-23-424	Repeal
R4-23-425	Repeal
R4-23-426	Repeal
R4-23-427	Repeal

R4-23-428	Repeal
R4-23-429	Repeal

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. § 32-1970

3. A list of all previous notices appearing in the *Register* addressing the proposed rules:

Notice of Rulemaking Docket Opening: 17 A.A.R. 1500, August 5, 2011 *(in this issue)*

4. The name and address of agency personnel with whom persons may communicate regarding the rules:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

5. An explanation of the rules, including the agency's reasons for initiating the rules:

S.B. 1298 passed by the 50th Legislature changed A.R.S. § 32-1970 to allow a pharmacist to enter into a protocol-based drug therapy management agreement with a provider to implement, monitor, or modify the drug therapy of a patient of the provider. The changes remove the requirement that drug therapy management must occur in a particular practice setting.

Because the statutory language has everything needed for a pharmacist to enter into a protocol-based drug therapy management agreement with a provider, we do not need the existing rules for drug therapy management in R4-23-421 through R4-23-429. The rulemaking will repeal the drug therapy management rules in R4-23-421 Drug Therapy Management, R4-23-422 Drug Therapy Management - Duties of the Board, R4-23-423 Drug Therapy Management Advisory Committee, R4-23-424 Drug Therapy Management - Pharmacist and Physician Qualifications, R4-23-425 Drug Therapy Management - Pharmacist Duties, R4-23-426 Drug Therapy Management - Physician Duties, R4-23-427 Drug Therapy Management - Documentation, R4-23-428 Drug Therapy Management - Quality Assurance, and R4-23-429 Drug Therapy Management - Privacy. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that repeal of these rules will benefit the public health and safety by reducing the rules burden and allowing the statutory standards to be used to clearly establish the standards for drug therapy management by pharmacists.

6. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on or not to rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The proposed rules will impact the Board, pharmacists, pharmacies, and the public. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The drug therapy management rules were put in place November 9, 2002. Since that time only five pharmacists received approval to perform drug therapy management. The previous statute and rules were very restrictive and only allowed drug therapy management to occur in hospitals, long-term care facilities, community health care centers, and health maintenance organization pharmacies. The process to get and maintain an agreement was very cumbersome. The Arizona Pharmacy Alliance worked with the health care providers to agree on a statute that allows drug therapy management to occur in any pharmacy practice setting. The statute requires an agreement between the provider, pharmacist, and patient based on written protocols for a pharmacist to implement, monitor, or modify the patient's drug therapy. Because of the way the statute was written, all the language prescribing the requirements for a pharmacist to enter into an agreement with a provider and perform drug therapy management under that provider's supervision, including necessary definitions, is in the statute, so we no longer need the existing rules. The rulemaking will repeal nine unnecessary Sections of rules.

The Board estimates the rulemaking will have a no impact on pharmacists and pharmacies.

The Board believes that repeal of these rules will benefit the public health and safety by reducing the rules burden and allowing the statutory standards to be used to clearly establish the standards for drug therapy management by pharmacists.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, September 6, 2011. An oral proceeding is scheduled for:

Date:	September 6, 2011
Time:	10:15 a.m.
Location:	1700 W. Washington St., 3rd Floor Board Room Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-421. ~~Drug Therapy Management~~ Repealed

~~A. A pharmacist qualified under R4-23-424 may provide drug therapy management under A.R.S. § 32-1970 after a physician's initial diagnosis of a patient if drug therapy management:~~

~~1. Is guided by a Board-approved drug therapy management agreement; and~~

~~2. Occurs in one of the following pharmacy practice sites:~~

~~a. An acute care hospital,~~

~~b. A nursing care institution,~~

e. A staff model HMO, or
d. A community health center as defined in A.R.S. § 32-1921 and A.R.S. § 36-2907.06.

B. A drug therapy management agreement shall contain the following:
1. The criteria and medical conditions under which the pharmacist may modify a patient's drug therapy;
2. The specific modifications of drug therapy that the pharmacist may make including drug, dose, and dosage form;
3. The criteria and medical conditions under which the pharmacist may implement a patient's drug therapy;
4. The specific drug therapy that a pharmacist may implement including drug, dose, and dosage form;
5. The subjective and objective patient assessment parameters that a pharmacist uses to evaluate a patient's drug therapy at each patient visit, including ordering and interpreting a patient's laboratory tests;
6. The subjective and objective patient assessment criteria that indicate when a pharmacist shall consult with a supervisory physician or if unavailable, an alternate physician, including the timing and nature of a consultation with or referral to a supervisory or alternate physician and the specific procedures for a consultation with or referral to a supervisory or alternate physician;
7. The content and frequency of the periodic status report on a patient that a pharmacist shall provide in writing to or in a meeting with the supervisory physician;
8. The procedure for terminating the drug therapy management agreement;
9. The names of the supervisory physician, the alternate physician, and the pharmacist authorized to provide services under the agreement; and
10. The signature of all persons named in subsection (B)(9).

R4-23-422. Drug Therapy Management – Duties of the Board Repealed

A. The Board shall:
1. Appoint a Drug Therapy Management Advisory Committee;
2. In consultation with Board staff and the Drug Therapy Management Advisory Committee, approve or deny an initial drug therapy management agreement and the annual renewal of an existing drug therapy management agreement;
3. Terminate a pharmacist's drug therapy management agreement if the pharmacist:
   a. Does not renew the agreement on or before the approval date anniversary; or
   b. Is found by the Board to lack the qualifications required in R4-23-424; and
4. In processing a drug therapy management agreement application, comply with the application process established in R4-23-602, except the substantive review time-frame is 180 days and the overall time-frame is 200 days.

B. The Board may terminate a pharmacist's drug therapy management agreement if the Board determines that the pharmacist is violating the requirements of the drug therapy management agreement or federal or state drug laws.

R4-23-423. Drug Therapy Management Advisory Committee Repealed

A. The Drug Therapy Management Advisory Committee shall:
1. Consist of an osteopathic physician, an allopathic physician, and two pharmacists with prior or current experience in drug therapy management;
2. Serve at the pleasure of the Board;
3. Serve for a term of two years unless removed or reappointed by the Board;
4. Review initial and renewal drug therapy management agreement applications; and
5. Advise the Board regarding the approval or denial of reviewed drug therapy management agreement applications.

B. The Drug Therapy Management Advisory Committee members are not eligible for compensation from the Board.

R4-23-424. Drug Therapy Management – Pharmacist and Physician Qualifications Repealed

A. Pharmacist qualifications.
1. Before initiating a drug therapy management agreement with a supervisory physician, a pharmacist shall have:
   a. A current, unrestricted license issued by the Board; and
   b. Proof of one of the following:
      i. Completion of a pharmacy practice residency accredited by the American Society of Health Systems Pharmacists or the American Pharmaceutical Association;
      ii. Current board specialty certification from the Board of Pharmaceutical Specialists or current certification as a Certified Geriatric Pharmacist;
      iii. A Doctor of Pharmacy degree and completion of an American Council on Pharmaceutical Education approved certificate program in each area of practice covered in the drug therapy management agreement; or
      iv. A Bachelor's degree in Pharmacy, satisfactory completion of an American Council on Pharmaceutical Education approved certificate program in each area of practice covered in the drug therapy management agreement, and appropriate credentialing issued by the governing body of a qualifying Arizona practice site described in A.R.S. § 32-1970.
2. To ensure that a pharmacist who provides drug therapy management is competent to continue providing the services delineated in a drug therapy management agreement, a pharmacist shall annually complete six contact hours (0.6

~~CEU's) of continuing education for each area of practice covered by the pharmacist's drug therapy management agreement. The continuing education hours may be used to satisfy the continuing education requirements for licensure as a pharmacist.~~

~~**B.** Supervisory physician qualifications. Before initiating a drug therapy management agreement with a pharmacist, a supervisory physician shall:~~

~~1. Have a current, unrestricted license from the Allopathic Board of Medical Examiners or the Board of Osteopathic Examiners in Medicine and Surgery; and~~

~~2. Not be a resident in a post-graduate medical training program.~~

~~**C.** Alternate physician qualifications. Before initiating a drug therapy management agreement with a pharmacist, an alternate physician shall:~~

~~1. Have a current, unrestricted license from the Allopathic Board of Medical Examiners or the Board of Osteopathic Examiners in Medicine and Surgery; and~~

~~2. Not be a resident in a post-graduate medical training program.~~

R4-23-425. ~~Drug Therapy Management – Pharmacist Duties~~ Repealed

~~**A.** To obtain initial approval for a drug therapy management agreement, a pharmacist shall submit a completed application, on a form furnished by the Board, that includes:~~

~~1. Pharmacist name and Arizona pharmacist license number;~~

~~2. Documentation of the pharmacist's qualifications as specified in R4-23-424;~~

~~3. Practice site name, address, mailing address if different, telephone number, and fax number;~~

~~4. Documentation of practice site qualification under A.R.S. § 32-1970;~~

~~5. Supervisory physician name, office address, mailing address if different, telephone number, and fax number;~~

~~6. Documentation of the supervisory physician's qualifications as specified in R4-23-424;~~

~~7. Alternate physician name, office address, mailing address if different, telephone number, and fax number;~~

~~8. Documentation of the alternate physician's qualifications as specified in R4-23-424;~~

~~9. Description of the pharmacist's practice area or areas for which approval is sought;~~

~~10. An original and 11 copies of the drug therapy management agreement covering each practice area for which Board approval is sought;~~

~~11. Dated and signed affirmation of the supervisory physician's acceptance of the responsibility for oversight of the pharmacist's drug therapy management;~~

~~12. Dated and signed affirmation of an alternate physician's acceptance of the responsibility for temporary oversight of the pharmacist's drug therapy management; and~~

~~13. Dated and signed affirmation of the pharmacist's acceptance of the responsibility to provide drug therapy management as described in the drug therapy management agreement.~~

~~**B.** To renew an existing drug therapy management agreement, a pharmacist shall submit a completed renewal application, on a form furnished by the Board, that includes, in addition to the requirements of subsection (A), the following:~~

~~1. Documentation that the supervisory physician, alternate physician, and participating pharmacist reviewed the protocols contained in the agreement;~~

~~2. Documentation that the participating pharmacist completed the continuing education requirements specified in R4-23-424; and~~

~~3. An original and 11 copies of the drug therapy management agreement covering each practice area for which renewal is sought, including highlighting any requested modifications to the agreement.~~

~~**C.** A pharmacist who participates in a Board-approved drug therapy management agreement shall:~~

~~1. Renew the agreement annually on or before the initial approval date anniversary;~~

~~2. Before submitting the application to renew the agreement, participate with the supervisory physician in reviewing the agreement;~~

~~3. Notify the Board within ten days of termination of the drug therapy management agreement;~~

~~4. During the first appointment with a patient under a Board-approved drug therapy management agreement:~~

~~a. Verify that a copy of the drug therapy management agreement, which includes the signature of the supervisory physician, alternate physician, and pharmacist, is placed in the patient's medical record;~~

~~b. Verify that a copy of the supervisory physician's written order, which authorizes the pharmacist to collaboratively manage the patient's drug therapy, is placed in the patient's medical record; and~~

~~c. Verify that a copy of the patient's written consent, which shows that the patient understands the pharmacist's role in the patient's care, the nature of the relationship with the supervisory physician, and the procedure for revoking consent, is placed in the patient's medical record;~~

~~5. Ensure compliance with the documentation requirements of R4-23-427;~~

~~6. Ensure compliance with quality assurance program required in R4-23-428;~~

~~7. Ensure compliance with the privacy requirements of R4-23-429; and~~

~~8. Comply with the Board-approved drug therapy management agreement.~~

R4-23-426. ~~Drug Therapy Management - Physician Duties~~ Repealed

~~**A.** Before referring a patient to a pharmacist, a supervisory physician who participates in a Board-approved drug therapy management agreement shall:~~

~~1. Have a physician-patient relationship with the patient and make a diagnosis of the patient;~~
~~2. Review the approved drug therapy management agreement with the patient;~~
~~3. Obtain the patient's consent to participate in the drug therapy management agreement;~~
~~4. Document the patient's consent to participate in the drug therapy management agreement by obtaining the patient's dated and signed consent that states that the patient has read, understood, and agreed to participate in the drug therapy management agreement. The dated and signed consent shall be placed in the patient's medical records;~~
~~5. Authorize a specific pharmacist to collaboratively manage a patient's drug therapy by placing a written order in the patient's medical record; and~~
~~6. Place a copy of the approved drug therapy management agreement in the patient's medical record to provide notice to other health care providers of the drug therapy management.~~

~~**B.** Physician supervision. A supervisory physician who supervises a pharmacist under a Board-approved drug therapy management agreement shall:~~

~~1. Before submitting the application to renew the agreement and in consultation with the participating alternate physician and pharmacist, review and approve the drug therapy management agreement;~~
~~2. Review and initial the pharmacist's documented care for appropriateness of care and compliance with the drug therapy management agreement when the patient visits the supervisory physician for follow-up or any other services;~~
~~3. Routinely evaluate the patient care provided by the pharmacist as specified in the drug therapy management agreement; and~~
~~4. Ensure that the supervisory physician or the alternate physician is readily available to the pharmacist for consultation, assistance, and direction by direct telecommunication or physical presence at the practice site.~~

~~**C.** Alternate physician duties. An alternate physician who participates in a Board-approved drug therapy management agreement shall ensure that the alternate physician is available to:~~

~~1. Temporarily assume responsibility for supervision and evaluation of the drug therapy management performed by the pharmacist;~~
~~2. Provide consultation, assistance, and direction to the pharmacist when the supervisory physician is unavailable; and~~
~~3. Before submitting the application to renew the agreement, participate with the supervisory physician and pharmacist in reviewing the agreement.~~

R4-23-427. ~~Drug Therapy Management - Documentation~~ Repealed

~~Documenting pharmacist-provided drug therapy management. A pharmacist who participates in drug therapy management under a Board-approved drug therapy management agreement shall:~~

~~1. After each patient-pharmacist appointment, document the drug therapy management for the patient in the patient's medical record at the practice site, including patient data, assessment of patient status, and treatment plan;~~
~~2. Date and sign the documentation required in subsection (1) in a patient's medical record with the pharmacist's first and last name, title, and Arizona pharmacist license number;~~
~~3. Document a consultation with or referral to the supervisory physician or the alternate physician; and~~
~~4. Document a consultation with a supervisory or alternate physician that results in a pharmacist's need to generate the physician's verbal prescription order for a drug not included in the drug therapy management agreement. The documentation shall include:~~
~~a. The phrase "verbal order by Dr." and the name of the supervisory physician or alternate physician authorizing the verbal prescription order,~~
~~b. The date and signature of the pharmacist generating the verbal prescription order in the same manner described in subsection (2), and~~
~~c. The countersignature of the supervisory physician or alternate physician authorizing the verbal prescription order within 72 hours of the pharmacist-generated verbal prescription order.~~

R4-23-428. ~~Drug Therapy Management - Quality Assurance~~ Repealed

~~**A.** A pharmacist who provides drug therapy management shall, in cooperation with the supervisory physician and the appropriate committee of the practice site, develop and implement a continuous quality assurance and improvement program that includes standards and procedures to identify, evaluate, and improve the quality of pharmacist-provided drug therapy management.~~

~~**B.** Periodic status reports or meetings between a pharmacist and supervisory physician regarding care of a patient under the drug therapy management agreement shall include evaluating and documenting patient status and the quality of care provided by the pharmacist.~~

R4-23-429. ~~Drug Therapy Management - Privacy~~ Repealed

~~**A.** A pharmacist who provides drug therapy management shall perform drug therapy management activities in a private and distinct area of the practice site.~~

~~**B.** In a practice site where a pharmacist provides drug therapy management under a drug therapy management agreement, a pharmacy permittee shall ensure that a private and distinct area of similar size and environment to that used by other primary care providers at the practice site is available for the performance of pharmacist-provided drug therapy management activities.~~